PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	05 MAY 2005
Applicant's or agent's file reference VS:CE:FP21350	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/AU2005/000403	21 March 2005	26 March 2004

International Patent Classification (IPC) or both national classification and IPC
Int. Cl.[7] A61K 38/12, A61P 25/28

Applicant
PROMICS PTY LIMITED et al

1. This opinion contains indications relating to the following items:

[X]	Box No. I	Basis of the opinion
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[X]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**JASON MACKENZIE** Telephone No. (02) 6283 7934

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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10/594358
PCT/AU2005/000403

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	20-22	YES
	Claims	1-19, 23-31	NO
Inventive step (IS)	Claims		YES
	Claims	1-31	NO
Industrial applicability (IA)	Claims	1-31	YES
	Claims		NO

2. Citations and explanations:

D1 WO 2005/007087 A2 (NEUROGEN CORPORATION) 27 January 2005 (see box VI)

D2 WO 2003/033528 A1 (UNIVERSITY OF QUEENSLAND) 24 April 2003

D3 EP 1308438 A1 (MITSUBISHI PHARMA CORPORATION) 7 May 2003

D4 Gasque P, Dean YD, McGreal EP, VanBeek J, Morgan BP. Complement components of the innate immune system in health and disease in the CNS. Immunopharmacology. 2000 Aug;49(1-2):171-86

D5 Farkas I, Takahashi M, Fukuda A, Yamamoto N, Akatsu H, Baranyi L, Tateyama H, Yamamoto T, Okada N, Okada H. Complement C5a receptor-mediated signaling may be involved in neurodegeneration in Alzheimer's disease. J Immunol. 2003 Jun 1;170(11):5764-71.

D6 Osaka H, McGinty A, Hoepken UE, Lu B, Gerard C, Pasinetti GM. Expression of C5a receptor in mouse brain: role in signal transduction and neurodegeneration. Neuroscience. 1999;88(4):1073-82.

Novelty (N) claims 1-19 and 23-31

The claims are directed to a method of treating a neurological or neurodegenerative condition involving inflammation using an inhibitor of C5a receptor.

D2 is considered to be the closest prior art, and discloses C5a receptor modulators that are useful in treating Parkinson's disease (see the passages recited in the ISR), which is known to have an inflammatory component. As such, D2 is considered to deprive claims 1-19 and 23-31 of novelty.

D3 also discloses the use of C5a receptor modulators in a method of treating a neurological or neurodegenerative condition involving inflammation (see the passages cited in the ISR). D3 differs from the current application in the choice of modulator, and as such only deprives claims 1-2, 12-14, 18-19, 23-27, and 29-31 of novelty.

(see also further comments at box V1 re D1)

None of the documents disclose the use of C5a receptor modulators in the treatment of the specific conditions defined in claims 20-22.

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International application No.
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Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
WO 2005/007087 A2	27 January 2005	30 June 2004	3 July 2003

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 15 derives features of the invention from another unpublished PCT application. It is considered that claim 15 does not satisfy the requirements of Article 5.

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10/594358

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Inventive Step (IS) claims 1-31.

D4 and D5 both discuss the involvement of C5a receptor in neurodegeneration (see the passages cited in the ISR). In particular, D5 proposes the use of specific receptor antagonists in the search for new drugs that might control the pro-inflammatory activities of C-derived fragments such as C5a (see the last paragraph of the discussion) The teaching of either document may be combined with D3, and therefore claims 1-2, 12-14, 18-19, 23-27, and 29-31 are deprived of an inventive step.

Also, the teaching of either of D4 or D5 may be combined with that of D2, and therefore claims 1-31 are deprived of an inventive step.

D6 teaches that the C5a receptor may be associated with neurodegeneration in the mouse brain (see the passages cited in the ISR). D6 does not suggest inhibition of C5a or its receptor.

With regard to the document(s) listed in Box VI under "certain documents cited", these are documents published prior to the international filing date but later than the priority date claimed but which would otherwise be considered to be of particular relevance.

Under the PCT, novelty is considered only in respect of documents published before the priority date. The relevance of a document published after the priority date is dependent upon national law. Such documents are excluded from consideration in preliminary examination, under the PCT Guidelines but have been included here for information. The priority date is considered to be valid.

Industrial Applicability (IA)

All of claims 1-31 are industrially applicable.